

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Jessica R. DesNoyer, et al.

Group Art Unit: 1792

Serial No.: 10/750,312

Examiner: Lamb, Brenda A.

Filed: 12/30/2003

CONFIRMATION NO: 1694

For: STENT MANDREL SUPPORT AND  
METHOD FOR COATING STENTS**Mail Stop Appeal Brief-Patents**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**AMENDED APPEAL BRIEF**

Dear Sir:

On March 12, 2008 Applicants timely appealed to the Board of Patent Appeals & Interferences (the "Board") from the Final Rejection of Claims 1, 4-9, 11, 13, 14, and 19-25, which have been twice rejected. The following is Applicants' Appeal Brief submitted under 37 C.F.R. § 41.37.

This "Amended" Appeal Brief is submitted in response to a 4/23/08 Notice of Non-Compliant Appeal Brief, which indicated that Applicants' brief did not comply with 37 CFR § 41.37(c)(1)(v) ("Summary of Claimed Subject Matter"). Applicants wish to extend their thanks to Specialist Tyson for his assistance in this matter. According to Specialist Tyson, Applicants' brief would comply with the requirements of Section 41.37(c)(1)(v) if citation were made to examples in the drawings and detailed descriptions for each of the independent claims described in the penultimate paragraph on page 4. This has been done. Accordingly, it is believed that Applicants' Amended Appeal Brief complies with all requirements of 37 C.F.R. § 41.37.

### **REAL PARTY IN INTEREST**

The real party in interest with regard to this appeal is Abbott Cardiovascular Systems, Inc., with its primary place of business at 3200 Lakeside Drive, Santa Clara, California 95054. Abbott Cardiovascular purchased the vascular device division and all relevant intellectual property including the instant application, of Advanced Cardiovascular Systems, also known as Guidant Corporation, in April 2006. The original assignment to Advanced Cardiovascular Systems was recorded at Recl/Frame 015350 / 0532 on May 20, 2004.

### **RELATED APPEALS AND INTERFERENCES**

There are no appeals or interferences related to or that might have any bearing, direct or indirect, on the Board's decision in this appeal.

### **STATUS OF CLAIMS**

Claims 1-15 and 18-26 are pending.

Claims 16, 17 were canceled.

Claims 2, 3, 10, 12, 15, 18 and 26 stand withdrawn.

Applicants are appealing to the Board the rejections of Claims 1, 4-9, 11, 13, 14, and 19-25, of which Claims 1, 9, 19, 20, 23 and 24 are independent claims.

### **STATUS OF AMENDMENTS**

There were no claim amendments presented in Applicants' Feb. 12, 2008 Request for Reconsideration, which was filed in response to the Dec. 12, 2007 Final Office Action.

### **SUMMARY OF CLAIMED SUBJECT MATTER**

Applicants invention is directed, at least in part to seeking a cure for the problem of how to spray the abluminal and side surfaces of a stent, but not the luminal surface, while minimizing contact with the stent during coating. On the one hand, there is a desire for not placing the stent in contact with the mandrel surfaces. On the other hand, if there are no mandrel surfaces to shield the luminal surfaces during spraying, then the coating substance will reach the luminal surfaces.

See Applicants' Specification at pg. 3, line 4 through pg. 4, line 5 (provided as **Exhibit A**). The solution to this problem was found in the design of a mandrel. See *Id.* at pg. 5, lines 3-9.

FIGS. 4-10 (**Exhibit A**) depict examples of mandrels suited for preventing coating substance from reaching a stent luminal surface while minimizing the contact points. FIGS. 3A-3B (**Exhibit A**) depict an example of a mandrel assembly having a mandrel 24 according to one or more of the embodiments described in FIGS. 4-10.

Independent Claim 1 is directed to a stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts. The support includes the feature of a third member extending through a longitudinal bore of the stent, and the third member shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the stent during application of a coating substance to the stent.

Examples of the support in Claim 1 are found in pages 11-12 and FIGS. 3A-3B of **Exhibit A**. In these examples, mandrel 24 would be an example of a third member. An example of a third member that has a plurality of spikes according to Claims 4 and 6 may be found in the embodiment of a mandrel 24 depicted in FIGS. 5A-5B. See page 17, line 10 – page 18, line 12 of **Exhibit A**.

Independent Claims 9, 19, 20, 23 and 24 are directed to a stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. See e.g., FIG. 1, page 1, lines 21-24; FIG. 2 and 3a, page 9, line 19 – page 10, line 16. Claim 9 describes a member that has outward projecting walls. See e.g., FIG. 5A, 5B, 5C, page 17, lines 10-14. Claim 19 describes a member that has 6 non-parallel sides. *Id.* Claim 20 describes a member that has at least three sides and a wall extending from each of the sides in an outwardly direction. *Id.* Claim 23 describes a member including outwardly projecting walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle. *Id.* And Claim 24 describes a member including a first end and a second end and at least 3 sides extending between the first and second end. *Id.* Support for the subject matter of Claims 9, 19, 20, 23 and 24 may also be found at page 13, lines 10-22; page 17, line 10 – page 21, line 4; and FIGS. 4-10 of **Exhibit A**.

The complete claim set is provided in the **Claims Appendix**.

## GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The issue(s) presented in this appeal is/are:

Whether Claims 1 and 4-8 are obvious under 35 U.S.C. § 103(a) as unpatentable over U.S. Pat. No. 4,846,791 to Hattler et al. (hereinafter "*Hattler*") in view of U.S. Pat. No. 5,674,208 to Berg et al. ("*Berg*").

Whether Claims 1 and 4-8 are obvious under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of U.S. Pat. No. 5,389,106 to Tower ("*Tower*").

Whether Claims 9, 11, 13-14 and 19-25 are obvious under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of U.S. Pat. No. 4,762,128 to Rosenbluth ("*Rosenbluth*") and prior art allegedly admitted by Applicants.

## ARGUMENT

### **I. The rejection of Claims 9, 11, 13-14 and 19-25 under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of *Rosenbluth* and prior art allegedly admitted by Applicants**

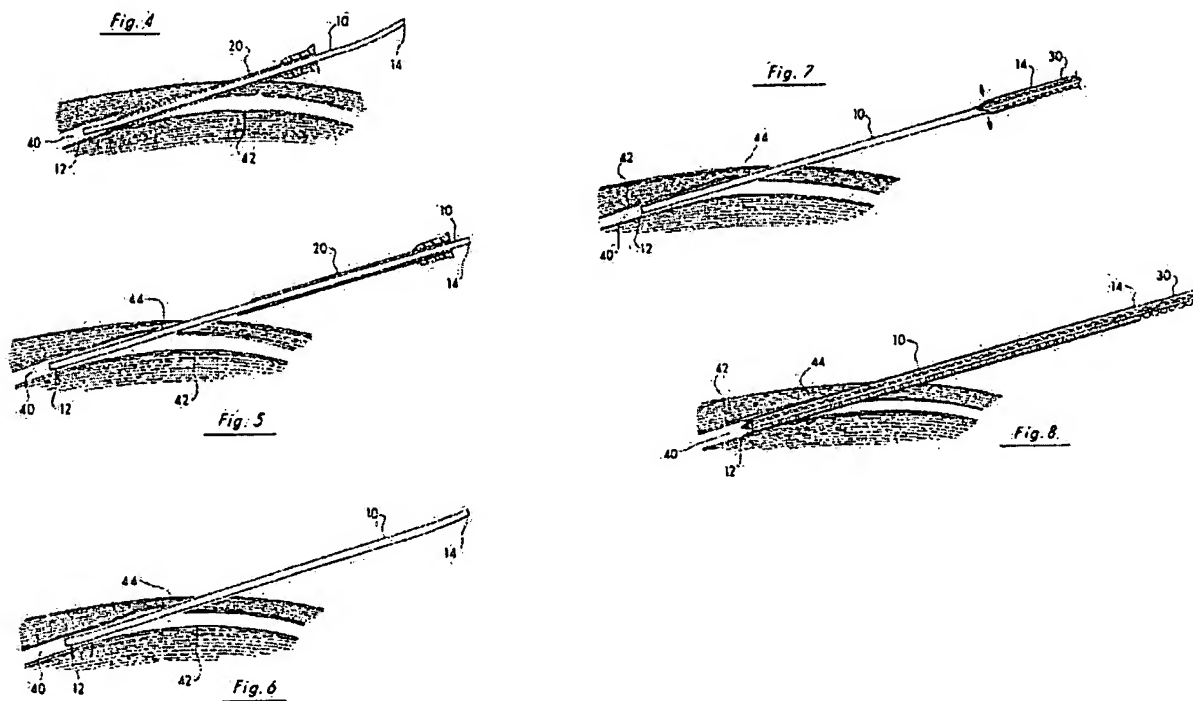
The Office's rejections of Applicants' claims are based, in large part, on the disclosure in *Hattler*. This reference discloses a multi-lumen catheter consisting of a flexible tube and divider. The divider is inserted into the tube after the tube is inserted into a patient's blood vessel. As best understood, the Examiner concluded that any type of stent (including scaffolding-type stents) could be used in place of *Hattler*'s tube. Also, the Examiner appears to have concluded that in view of *Rosenbluth*'s inflation catheter one of ordinary skill would have recognized that *Hattler*'s divider structure has an established function as a mandrel support for any type of stent. The relevant features of *Hattler* are discussed before addressing the merits of the rejections. A copy of *Hattler* is provided as **Exhibit B**.

#### **A. *Hattler*'s Multi-Lumen Catheter**

*Hattler* is directed to a multi-lumen catheter suited for delivering several medications to a patient using a single, embedded catheter tube having multiple lumens. *Hattler*'s catheter

consists of a flexible tube 10 and divider piece 30 inserted into the tube 10 after the tube has been inserted into a blood vessel. *See* col. 2, ll. 15-30.

FIGS. 4-8 (reproduced below) depict, step-by-step, how the multi-lumen catheter is assembled. First, a flexible tube 10 is inserted into a hollow needle 20. Then the needle 20 is used to deliver the tube 10 to the blood vessel. Next, the needle 20 is removed so that one end 14 of the tube is outside the patient and the other end 12 is within the patient. Next the divider piece 30 is introduced to form the multiple lumens within the tube.



FIGS. 4-8 of *Hattler*

(needle 20 inserts flex tube 10 into blood vessel 42; needle 20 is removed; then divider 30 is inserted into tube 10)

According to *Hattler*, during the steps depicted in FIGS. 7-8 a divider 30 is

inserted into the catheter tube from the distal end 14 of the tube, as shown in FIG. 7, thereby dividing the tube into a plurality of separate lumens. . . . As the divider is inserted into the tube, each of the outer edges or corners 32 of the divider contact the inside surface of the tube to form a fluid-tight seal extending the length of the divider between adjacent lumens.

Col. 4, ll. 45-60 (emphasis added). Thus, in this embodiment the divider 30 forms fluid tight seals when inserted into the tube 10. Referring to FIG. 3, these seals are formed by the tips

32 of the triangular divider 30 pressed into the walls of the tube 10. According to *Hattler* FIG. 3 depicts a multi-lumen catheter with four separate, fluid-tight lumens (shown is three separate spaces between the sides 34 of the divider 30 and inner walls of the tube 10, and a fourth lumen formed by the area 36 within the divider). In all other embodiments of *Hattler* the divider 30 is shaped to provide multiple types of lumens all of which are designed to form a fluid tight seal between walls of divider 30 and inner wall of the tube 10. See e.g. col. 6, ll. 60-63 (forming grooves to insure a better seal); and FIGS. 11-17.

*Hattler* requires fluid-tight seals between the tube 10 and the divider 30 because the only conceivable purpose of *Hattler* is “catheters having multiple fluid carrying passageways.” Col. 1, ll. 6-8. In the background section it becomes evident why this is the case. *Hattler* insists upon fluid-tight seals because he is concerned with finding a replacement for multiple catheters for delivery of fluids into and out of the body. Col. 1, ll. 18-24. Multiple lumens “allows a number of different medications to be administered to the patient at one time using the same catheter.” *Id.* According to *Hattler*, the solution to the problems in the prior art is to have a divider that is “separately inserted into the catheter tube after the tube has been introduced into the blood vessel, thereby providing multiple lumens for the catheter.” Col. 2, ll. 15-23.

#### B. Independent Claims 9, 19, 20, 23 and 24

The Office’s basis for rejecting Claim 9 (as well as the other claims subject to the same rejection) appears to be little more than a conclusory statement that this claim would have been obvious in view of the disclosure in *Hattler*, Applicants’ disclosure of stent structures, and *Rosenbluth*’s disclosure of the concept of coating a stent while it is mounted on a balloon catheter. However, the Office does not carry its burden by merely describing what is in the various cited references. A *prima facie* case of obviousness can only be made if the Office first undertakes a *Graham* analysis, which requires making specific factual findings; then provides an explicit reason why, based on the *Graham* findings, Claim 9 would have been obvious at the time of the invention. See *KSR Int’l v. Teleflex*, 127 S.Ct. 1727, 1740-41 (2007) ; MPEP § 2143. The Final Office Action does not articulate what (if any) findings were made as to the scope of the prior art or the level of ordinary skill. Nor does the Final Office Action articulate an explicit reason why, in light of at least these *Graham* findings, Claim 9 would have been obvious. Instead, the Official Action simply states that it would have been obvious to modify the art in

order to arrive at Claim 9. This is an improper basis for rejecting Applicants' claims under Section 103.

For at least this reason Applicants respectfully ask that the Board reverse the Examiner's findings for Claim 9 because the Office appears to have failed to base its conclusions of obviousness on the *Graham* factors as required, *KSR Int'l*, 127 S. Ct. at 1734, and also failed to provide an explicit reason as to why one of ordinary skill in the art would have found it obvious to practice Claim 9 based on these *Graham* factors, as also required. *Id.* at 1740-41.

\* \* \*

Even assuming the Office undertook a proper *Graham* analysis, for at least the following two reasons no combination of the cited prior art provides a valid basis for concluding that Claim 9 would have been obvious under 35 U.S.C. § 103(a) at the time of the invention. First, the combined prior art would have rendered *Hattler* inoperable and/or *Hattler* would have taught away from Claim 9. Second, the only explanation, on record, for making the alleged combination of the prior art at the time of the invention would have been that described in Applicants' specification, i.e., the solution to the problem of coating the underside of a stent while making minimum contact with the stent, as discussed above. Accordingly, there could not have been a *prima facie* case of obviousness because the combination of prior art is forbidden based on being tainted by hindsight.

As noted above, Claim 9 is directed to a stent and a mandrel supporting the stent. The claim includes the feature of a stent that has a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts and the mandrel includes a member including outward projecting walls. According to the Final Office Action (**Exhibit C**), and as confirmed in the Advisory Action of 3/6/08 (**Exhibit D**), Claim 9 stands rejected because the Examiner found that *Hattler*, in combination with other prior art, would have rendered Claim 9 obvious.

*Hattler* describes a multi-lumen catheter. As defined by *Hattler*, col. 1, ll. 5-24 and col. 2, ll. 1530, a multi-lumen catheter delivers different therapeutic substances to the body intravenously. Accordingly, in order for it to work, a multi-lumen catheter must have fluid-tight passageways. The passageways in *Hattler*'s catheter are formed by inserting a divider structure into a flexible tube (see FIG. 1, above). Notably, *Hattler* mentions, or at least implies at several

locations the need for forming “fluid-tight” seals between the divider and tube walls, *see e.g.* col. 2, ll. 15-30, col. 4, ll. 52-64; and col. 6 ll. 53-65, obviously because the catheter, in order to function properly, must be capable of providing fluid-tight passageways. Thus, if the seals or tube walls are not fluid tight, the catheter cannot function properly. *See e.g.*, the use configuration in FIG. 8 of *Hattler*.

Claim 9, in contrast to the prior art, is directed to a stent and a mandrel supporting the stent. The stent includes the feature of abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. Thus, a fluid freely passes in and out of the space between the stent walls and the walls of the mandrel according to the apparatus of Claim 9. If *Hattler*’s catheter were modified by replacing the tube with the stent described in Claim 9, this catheter would no longer function properly. That is, the catheter would be rendered inoperable.

“[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious.” *KSR Int’l Co. v. Teleflex Inc. et al.*, 127 S. Ct. 1727, 1740 (2007). “There is no suggestion to combine, however, if a reference teaches away from its combination with another source.” *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant... [or] if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.” *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2D (BNA) 1130, 1131 (Fed. Cir. 1994). “If when combined, the references ‘would produce a seemingly inoperative device,’ then they teach away from their combination”: *Tec Air*, 192 F.3d at 1360; *see also In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. (BNA) 1125, 1127 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose).

Thus, a claim could not have been obvious if the combined prior art would have rendered the prior art inoperable. Under any reading of *Hattler*, the multi-lumen catheter would have been rendered inoperable if the tube 10 was replaced with a stent having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts. And



there would have been no other purpose for the divider in *Huttler* then to create fluid-tight passageways. Accordingly, for at least this reason Applicants ask that the Board reverse the Examiner's finding that Claim 9 would have been obvious under 35 U.S.C. § 103(a) in view of *Huttler*, *Rosenbluth* and the prior art allegedly admitted by the Applicants.

A question of obviousness "must be determined in light of all the facts, and there is no rule that a single reference that teaches away will mandate a finding of non-obviousness". *Medichem v. Rolabo*, 437 F.3d 1157, (Fed. Cir. 2006). Even assuming, however, that the teaching-away deficiencies in *Huttler* are not dispositive of the obviousness question, the Board should alternatively reverse the Examiner's rejection of Claim 9 because there is no rationale for the alleged combination in the record, other than to provide a solution to a problem that was identified by the Applicants (the Examiner fails to cite any prior art demonstrating that the problem identified by Applicants was known in the prior art).

As noted above, the Examiner never provided a reason for the alleged combination, although this is required under the law. *See KSR Int'l*, 127 S. Ct. at 1740-41. Applicants can only speculate, therefore, that the reason derived either from a motivating purpose that lead to Applicants' conception, i.e., the problem identified and solved by Applicants, which is improper, or some motivation implicit in the art of record. However, upon review of the art of record, Applicants conclude that there is nothing in the art that would have suggested or motivated one of ordinary skill (whether for Applicants' purpose or some other purpose) to modify *Huttler* in the manner suggested.

As explained above, Applicants sought to cure the problem of how to spray the abluminal and side surfaces of a stent, but not the luminal surface. The solution to the problem was found in the design of the mandrel. As such Claim 9 describes a member including the feature of "outwardly projecting walls". The prior art of record, however, provides no alternative motivation or rationale. *Huttler* obviously provides no motivation for the alleged combination. As to *Rosenbluth*, this reference shows a stent mounted on a balloon catheter. *See* FIGS. 1-8 (provided as **Exhibit E**). A stent is mounted on a balloon catheter according to *Rosenbluth* so that it can be delivered to a sight in the body. But there is no rationale provided in this reference that would explain why one of ordinary skill would have used *Huttler*'s divider to mount a stent or would have replaced a balloon catheter with a divider.

As best understood, the Examiner found that one of ordinary skill would have been motivated in view of *Rosenbluth* to mount a stent on anything capable of functioning as a mandrel. *See e.g.*, Advisory Action of 3/6/08 (provided as **Exhibit D**). Applicants assume, therefore, the Examiner concluded that Claim 9 would have been obvious because the claim is nothing more than a mere substitution of known elements to yield predictable results. *See* MPEP § 2143. The Examiner's analysis (assuming Applicants' understanding is correct), however, is fundamentally flawed because it never provides a reason why one of ordinary skill would have known or concluded that the divider 30 has an established function of supporting a stent. The divider 30 is inserted into a flexible tube. Its function is to form fluid-tight passageways while allowing the assembled catheter to be adequately flexible to conform to the natural curvature of a blood vessel. *See* FIG. 8 of *Hattler*. One of ordinary skill would have concluded, therefore, that a tube 10 as described by *Hattler* is clearly not the same thing as a stent. Thus, *Hattler*'s divider 30 would not have had an established function of supporting a stent according to one of ordinary skill in the art. ***Indeed, Hattler's divider 30 has an established function of supporting a stent to the same extent that a pencil has an established function of supporting a stent.*** While both may be capable of supporting a stent, it can hardly be said that stent-supporting is an "established function" of either of these structure.

There being no established function to support a stent, a rationale of "combining known elements to yield predictable results", MPEP § 2143, does not apply here. Therefore, no basis exists to reject Claim 9 under 35 U.S.C. § 103(a). For this additional reason Applicants also ask that the Board reverse the rejection of Claim 9 under 35 U.S.C. § 103(a).

For similar reasons as those given for Claim 9, Applicants also ask that the Board reverse the Examiner's rejection of independent Claims 19, 20, 23 and 24 under Section 103.

**C. Dependant Claims 11, 13, 14, 21, 22 and 25**

Claims 11, 13, 14, 21, 22 and 25 depend from Claims 9, 20 and 24, respectively, and recite additional features that further distinguish Applicants' invention over the art of record. However, it is not necessary to point out the additional features recited in these dependant claims. Because Claims 11, 13, 14, 21, 22 and 25 depend from allowable claims, they are also allowable. For this reason, Applicants ask that all standing the rejections of Claims 11, 13, 14, 21, 22 and 25 under 35 U.S.C. § 103 be withdrawn.

**II. The rejection of Claims 1 and 4-8 under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of *Berg***

**A. Claim 1**

The Examiner rejected Claim 1 in part because *Hattler* is believed to have suggested that tube 10 may be replaced with the claimed scaffolding-type stent. Applicants contend, however, that this rejection under Section 103 is improper because *Hattler* specifically teaches away from replacing the flexible tube 10 with a scaffolding-type stent. Applicants also traverse this rejection because the rejection relies on the incorrect view that *Hattler*'s meaning for a catheter is not limited to flexible tubes; rather, it covers any stent having a plurality of struts, including scaffolding-type stents ("stents") covered by Claim 1.

According to *Hattler* the tube 10 is made from flexible, expandable material such as amber latex, vinyl or silicon rubber. According to *Hattler* the tube 10 has little, if any radial stiffness. This highly flexible tube is evident from the disclosure, and also important to the operation of the catheter, for the following reasons: (1) the divider 30 actually needs supports 38 to prevent the walls of the tube 10 from collapsing when inserted into a blood vessel, *see* col. 5, ll. 25-44; (2) the tube 10 "must also have sufficient flexibility to allow it to follow the natural curvature of . . . [a] blood vessel", col. 4, ll. 27-29 of *Id* (emphasis added); and (3) a fluid-tight seal is formed by making the divider 30 outer dimensions larger than the tube's inner wall diameter (so that the tube is radially expanded in order to extend the divider into the blood vessel), *see* col. 4, ll. 61-64 (from this one of ordinary skill would have concluded that the tube 10 must have very little hoop, radial or bending stiffness in order for a divider 30 to have dimensions larger than the dimensions of the tube 10 to be inserted into the tube after the tube has been inserted into a curved blood vessel). Thus, for these reasons one of ordinary skill would have found that pursuing the course of replacing a flexible tube with a scaffolding stent counterproductive in view of *Hattler*. Accordingly, *Hattler* teaches away from replacing the tube 10 with a scaffolding stent because a scaffolding stent fails to provide any of the features outlined above; instead, a scaffolding stent would preclude such features. Claim 1 would therefore have not have been obvious over *Hattler* in combination with *Berg*. For this reason Applicants ask that the Board reverse the Examiner's rejection of Claim 1 in view of *Hattler* and *Berg*.

As Applicants clearly set forth in the specification, the stent in Claim 1 is one that provides radial stiffness to serve as scaffolding. *See* pg. 1 of **Exhibit A**. As just explained, such a structure would frustrate the requirements of the tube 10 in *Hattler*. Moreover, the Examiner has never explained or cited to evidence supporting the view that one of ordinary skill would have concluded that a tube as depicted in FIG. 8 is synonymous or equivalent to a stent that functions as scaffolding. These are entirely different devices. Indeed, Applicants have never even heard of a scaffolding-type stent that would be capable of being used in the manner depicted in FIG. 8.

As noted above, the Examiner's rejection relies on the premise that one of ordinary skill would have concluded that the meaning of catheter in *Hattler* includes a scaffolding type stent, which Applicants have demonstrated is clearly not the case. Therefore, the rejection of Claim 1 under 35 U.S.C. § 103(a) in view of *Hattler* and *Berg* cannot stand. For this reason Applicants ask that the Board reverse the Examiner's rejection of Claim 1.

**B. Claim 4**

Claim 4 recites a stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts, and wherein the third member has a plurality of spikes.

The Examiner rejected Claim 4 in part because *Hattler* is believed to have suggested that tube 10 may be replaced with the claimed scaffolding-type stent. Applicants contend, however, that this rejection under Section 103 is improper because *Hattler* specifically teaches away from replacing the flexible tube 10 with a scaffolding-type stent. Applicants also traverse this rejection because the rejection relies on the incorrect view that *Hattler*'s meaning for a catheter is not limited to flexible tubes, rather, it covers any stent having a plurality of struts, including scaffolding-type stents ("stents") covered by Claim 4.

For the same reasons as those set forth above for Claim 1, Applicants request that the Board reverse the rejection of Claim 4 because *Hattler* teaches-away from replacing the tube 10 with a stent as claimed in Claim 4. Applicants also request that the Board reverse the Examiner's findings because the rejection relies on the premise that one of ordinary skill would have concluded that the meaning of catheter in *Hattler* includes a scaffolding type stent, which Applicants have demonstrated is not the case. Therefore, the rejection of Claim 4 under 35 U.S.C. § 103(a) in view of *Hattler* and *Berg* cannot stand.

C. Claim 6

Claim 6 depends from 4 and recites “wherein the plurality of spikes do not contact the luminal surface of the stent”. This claim stands rejected as obvious over *Hattler et al* because it is believed that *Hattler* discloses an embodiment in which protrusions do not contact the tube. Applicants assume this statement is made in reference to the disclosure under col. 5, ll. 25-44 of *Hattler*.

The Examiner’s analysis is flawed. The reference passage in *Hattler* is actually referring to the situation in which the ends of the divider are such that there is sufficient support for the tube 10 (therefore, the protrusions are not needed). One example of such a divider structure would be that shown in FIG. 16. In these cases, the divider 30, due to its structure forms 6 passages and also adequately supports the walls of the flexible tube to prevent it from collapsing. Moreover, as should be apparent from the above discussion, *Hattler* would not function properly if the ends of the divider 30 did not touch the inner walls of the tube because a fluid-tight seal is needed.

Applicants submit that the Examiner has not made out a *prima facie* case of obviousness, either because the feature of “wherein the plurality of spikes do not contact the luminal surface of the stent” would have rendered *Hattler* inoperable or because the combined art does not teach every feature of the claim. For these reasons Applicants request that the Board reverse the rejection of Claim 6 under 35 U.S.C. § 103(a) in view of *Hattler* and *Berg*.

D. Dependant Claims 5, 7 and 8

Claims 5, 7 and 8 depend from Claim 1 and recite additional features that further distinguish Applicants’ invention over the art of record. However, it is not necessary to point out the additional features recited in these dependant claims. Because Claims 5, 7 and 8 depend from allowable claims, they are also allowable. For this reason, Applicants ask that the standing rejections of Claims 5, 7 and 8 under 35 U.S.C. § 103, respectively, be withdrawn.

**III. The rejection of Claims 1 and 4-8 under 35 U.S.C. § 103(a) as unpatentable over *Hattler* in view of *Tower***

**A. Claim 1**

For the same reasons as that given above under Section II.A Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**B. Claim 4**

For the same reasons as that given above under Section II.B Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**C. Claim 6**

For the same reasons as that given above under Section II.C Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**D. Dependant Claims 5, 7 and 8**

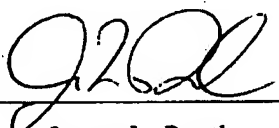
For the same reasons as that given above under Section II.D Applicants request that the rejection under 35 U.S.C. § 103(a) based on the combination of *Hattler* and *Tower* be reversed.

**CONCLUSION**

The Examiner has failed, as a matter of law, to set forth a case of obviousness under 35 U.S.C. § 103(a). Applicants therefore respectfully request that the Board reverse the rejections of the claims and order the application to be passed to issue.

Respectfully submitted,

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# CLAIMS APPENDIX

**WHAT IS CLAIMED:**

1. (previously presented) A stent and a stent mandrel support supporting the stent, the stent comprising a plurality of struts, the support comprising:
  - a first member to contact a first end of the stent;
  - a second member to contact a second end of the stent; and
  - a third member connecting the first member to the second member and extending through a longitudinal bore of the stent, the third member shaped and/or sized to eliminate or substantially prevent a coating from being formed on a luminal surface of the stent during application of a coating substance to the stent.
2. (withdrawn) The stent and support of claim 1, wherein the third member is cylindrical in shape.
3. (withdrawn) The stent and support of claim 2, wherein the outer diameter of the third member is about 1.35 mm to about 1.4 mm less than the inner diameter of the stent as positioned on the support.
4. (previously presented) The stent and support of claim 1, wherein the third member has a plurality of spikes.
5. (previously presented) The stent and support of claim 4, wherein the plurality of spikes contact the luminal surface of the stent.
6. (previously presented) The stent and support of claim 4, wherein the plurality of spikes do not contact the luminal surface of the stent.



7. (previously presented) The stent and support of claim 1, wherein the cross section of the third member is star shaped.
8. (previously presented) The stent and support of claim 1, wherein the cross section of the third member is "+" or "X" shaped.
9. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including outward projecting walls, the length of at least one of the walls being not less than 25% of the length of the stent.
10. (withdrawn) The stent and mandrel of claim 9, wherein a cross section of at least one of the walls is rectangular in shape.
11. (previously presented) The stent and mandrel of claim 9, wherein a cross section of at least one of the walls is triangular in shape.
12. (withdrawn) The stent and mandrel of claim 9, wherein at least one of the walls has a radius of curvature.
13. (previously presented) The stent and mandrel of claim 9, wherein the length of the wall is not less than 50% of the length of the stent.

14. (previously presented) The stent and mandrel of claim 9, wherein the length of the wall is equal to or greater than the length of the stent.

15. (withdrawn) A mandrel to support a stent during the application of a coating composition to the stent, comprising a mandrel body capable of being inserted at least partially into a longitudinal bore of a stent and a spiral wall circumscribing the mandrel body.

16-17. (canceled)

18. (withdrawn) A mandrel to support a stent during application of a coating substance to the stent, comprising: a member to penetrate at least partially into a longitudinal bore of the stent during the application of a coating substance, the member including 3 outward projecting walls, each wall including a pair of opposing parallel sides.

19. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including 6 non-parallel sides.

20. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a core section having at least three sides and a wall extending from each of the sides in an outwardly direction.

21. (previously presented) The stent and mandrel of Claim 20, wherein the walls are triangular in cross section, are square in cross section or have a curved shape.

22. (previously presented) The stent and mandrel of Claim 20, wherein the cross section of the core has a shape of a square, triangle, or rectangle.

23. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including outwardly projecting walls disposed around the circumference of the mandrel, wherein each of the walls converge with its neighboring wall at an angle.

24. (previously presented) A stent and a mandrel supporting the stent, the stent comprising a plurality of struts having abluminal surfaces and luminal surfaces in fluid communication through at least a pair of the plurality of struts, the mandrel comprising: a member penetrating at least partially into a longitudinal bore of the stent during the application of a coating substance to the stent, the member including a first end and a second end and at least 3 sides extending between the first and second end, the length of each side being at least 25% of the length of the stent.

25. (previously presented) The stent and mandrel of claim 24, wherein the length of each side is equal to or greater than the length of the stent.

26. (withdrawn) A method of coating a stent with a substance, comprising:  
supporting a stent on a stent mandrel support of claims 1 – 15 and 18-25; and  
applying a coating composition to the stent.

# **EVIDENCE APPENDIX**

Attached hereto are the following:

- Exhibit A:** Substitute Specification for U.S. Patent Application Serial No.: 10/750,312 (filed in response to 9/1/2005 Official Action)
- Exhibit B:** U.S. Pat. No. 4,846,791 to ("*Hattler*").
- Exhibit C:** U.S. pat. No. 4,762,128 to ("*Rosenbluth*").
- Exhibit D:** Final Office Action mailed December 12, 2007.
- Exhibit E:** Advisory Action mailed march 6, 2008.

# **RELATED PROCEEDINGS**

## **APPENDIX**

There are no related proceedings.